

## Patent Office of the People's Republic of China

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Applicant	LIFESCAN, INC.		Seal of Examiner	Date of Issue
Agent	China Patent Agent (H.K.) Ltd.			August 3, 2007
Patent Application No.	200410096000.2	Application Date	October 30, 2004	Exam Dept.
Title of Invention	LANCING DEVICE WITH TRIGGER MECHANISM FOR PENETRATION DEPTH CONTROL			

*First Office Action*

1. ☒ Pursuant to the provision of Article 35 (1) of the Chinese Patent Law, the examiner made an examination as to substance of the captioned patent application for invention upon the request for substantive examination filed by the applicant on \_\_\_\_\_.
- ☐ Pursuant to the provision of Article 35 (2) of the Chinese Patent Law, the Chinese Patent Office has decided to conduct on its own initiative an examination as to substance of the captioned patent application for invention.
2. ☒ The applicant requests taking the filing date, 2003.10.31, at the US Patent Office, the filing date, \_\_\_\_\_, at the \_\_\_\_\_ Patent Office, the filing date, \_\_\_\_\_, at the \_\_\_\_\_ Patent Office as the priority date of the present application.
- ☒ A copy of the first filed patent application certified by the receiving organ of the initial country of filing has been submitted by the applicant.
- ☐ A copy of the first filed patent application certified by the receiving organ of the initial country of filing has not been submitted by the applicant. Pursuant to the provision of Article 30 of the Chinese Patent Law, no priority right shall be deemed to have been claimed.
3. ☐ The applicant filed amended application document(s) on \_\_\_\_\_ and \_\_\_\_\_.
- ☐ Examination has confirmed that \_\_\_\_\_ filed on \_\_\_\_\_ cannot be accepted, \_\_\_\_\_ filed on \_\_\_\_\_ cannot be accepted,
- as the above amendment(s) ☐ is/are not in conformity with the provision of Article 33 of the Chinese Patent Law.
- ☐ is/are not in conformity with the provision of Rule 51 of the Implementing Regulations of the Chinese Patent Law.
- ☐ For the specific reason that the amendment(s) cannot be accepted, see the text of

the Office Action.

4. ☒ The examination is conducted in the light of the original application document(s)  
☐ The examination is conducted in the light of the following application document(s):  
in the original application documents submitted on the filing date:  
Claim(s) \_\_\_\_\_, page(s) \_\_\_\_\_ of the description, Figure(s)  
of the drawing(s); Claim(s) \_\_\_\_\_, page(s) \_\_\_\_\_ of the description,  
Figure(s) \_\_\_\_\_ submitted on \_\_\_\_\_; Claim(s) \_\_\_\_\_, page (s)  
of the description, Figure(s) \_\_\_\_\_ submitted on \_\_\_\_\_  
☐ Abstract of the description submitted on \_\_\_\_\_.
5. ☐ The present Office Action has been prepared without a search having been conducted.  
☒ The present Office Action has been prepared with a search having been conducted.  
☒ The following reference document(s) is/are cited in this Office Action (its/their serial number(s) will, continue to be used throughout the examination procedure):

No.	Number or Title of Document	Date of Publication (or filing date of interfering application)
1	WO03/007819A1	(Date) 2003.1.30
2	US6589260B1	(Date) 2003.7.8
3		(Date)
4		
5		
6		

6. The concluding comments of the examiner are:

- ☐ On the description:
- ☐ The content of the application comes within the scope where no patent right is granted as provided in Article 5 of the Patent Law.
  - ☐ The description is not in conformity with the provision of Article 26(3) of the Patent Law.
  - ☐ The drafting of the description is not in conformity with the provision of Rule 18 of the Implementing Regulations.
- ☒ On the claims:
- ☐ Claim comes within the scope where no patent right is granted as provided in Article 25 of the Patent Law.
  - ☐ Claim(s) is/are not in conformity with the definition of invention in Rule 2(1) of the Implementing Regulations.
  - ☒ Claim(s) 1-2.5, 10 does/do not possess novelty as provided in Article 22(2) of the Patent Law.
  - ☒ Claim(s) 3-4.6-9 does/do not possess inventiveness as provided in Article 22(3) of the Patent Law.
  - ☒ Claim(s) 11-13 does/do not possess inventiveness as provided in Article 22(4) of the Patent Law.

- ☐ Claim(s) \_\_\_\_\_ is/are not in conformity with the provision of Article 26(4) of the Patent Law.
- ☐ Claim(s) \_\_\_\_\_ is/are not in conformity with the provision of Article 31(1) of the Patent Law.
- ☐ Claim(s) \_\_\_\_\_ is/are not in conformity with the provisions of Rule 20 of the Implementing Regulations.
- ☐ Claim(s) \_\_\_\_\_ is/are not in conformity with the provision of Article 9 of the Patent Law.
- ☐ Claim(s) \_\_\_\_\_ is/are not in conformity of the provision of Rule 23 of the Implementing Regulations.

For specific analyses of the above concluding comments, see the text of this Office Action.

7. In view of the above concluding comments, the examiner holds that:

- ☐ The applicant should amend the application document in accordance with the requirements raised in the text of this Office Action. The amended document(s) should be submitted in duplicate and should conform to the provisions of Article 33 of the Patent Law and Rule 51 of the Implementing Regulations of the Chinese Patent Law.
- ☐ The applicant should expound in his Observations the reasons why the captioned patent application is patentable and amend the places not conforming to regulations as pointed out in the text of the Office Action, otherwise it would be impossible for the patent right to be granted.
- ☒ The captioned patent application contains no substantive content for which the patent right may be granted, thus if the applicant has not advanced his reasons or has not done so adequately, the application will be rejected.

8. The applicant should pay attention to the following matters:

- (1) In accordance with the provision of Article 37 of the Patent Law, the applicant should submit his/its Observations within **four** months from the date of receipt of this Office Action; if, without any justified reason, the time limit for making response is not met, the application will be deemed to have been withdrawn.
- (2) The amendments made by the applicant to his application should conform to the provision of Article 33 of the Patent Law, the amended text should be in duplicate and the format should conform to the relevant provisions of the Guidelines for Examination.
- (3) The applicant's Observations or amended text should be mailed or presented to the Receiving Section of the Chinese Patent Office. Document not mailed or presented to the Acceptance Section have no legal force.
- (4) Without making an appointment, the applicant and/or agent may not come to the Chinese Patent Office to hold an interview with the examiner.

9. This Office Action consists of the text portion totalling 3 page(s) and of the following annex(es):

☒ 2 duplicate copies of the reference document(s) cited totalling 56 page(s).

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### **The First Office Action (Text)**

The present application relates to a lancing device with trigger mechanism for penetration depth control. Specific comments are given hereunder after the present case has been examined.

1. Claims 11-13 fail to comply with the provision regarding practical applicability as set out in Article 22.4 of the Chinese Patent Law for the following reasons:

Claims 11-13 are directed to a method for lancing a target site. According to the description on page 1, "penetrate a dermal tissue target site; a biological fluid sample (e.g., a whole blood sample) can then be expressed from the penetrated target site". Therefore, this method is a trauma processing method carried out on a living human being/animal. This kind of surgical method not for treatment purpose cannot be applied in industries, and therefor lacks practical applicability.

2. Claim 1 lacks novelty under Article 22.2 of the Chinese Patent Law.

Claim 1 is directed to a lancing device. D1 (WO03/007819A1), directed to a piercing device, has specifically disclosed the following technical features (see Fig. 19; pages 6-7 and 10-11 and 19 of D1): "the piercing device comprising: a housing 2 constituted by a cylindrical element 20; a lancing mechanism 3 operatively attached to the housing 2, a pressure tip 8 containing an analysis sensing unit 4 and engaging a target site on the skin and creating a target site bulge, the pressure tip moveably attached to the housing via a biasing spring 83; and a trigger mechanism composed of a bracket 7B of the analysis sensing unit and a pivoting member 79 to detect the height of a target site bulge and trigger an immobilization of the pressure tip with respect to the housing". It can be seen that D1 has already disclosed all the technical features of claim 1 of the present application and that the technical solutions of D1 and claim 1 are the same, fall into the same technical field, solve the same technical problem of providing a lancing device that can control the penetration depth, and can

result in the same technical effects. Therefore the claimed technical solution of claim 1 lacks novelty under Article 22.2 of the Chinese Patent Law.

3. Claims 2, 5, 10 lack novelty under Article 22.2 of the Chinese Patent Law.

Dependent claim 2 further defines claim 1. Fig.19 of D1 discloses that a bias spring 83 applies a pre-pressure against the cylindrical unit 8 of the pressure tip, that is to say, d1 discloses the additional technical features of claim 2. Accordingly, when claim 1 is not novel, claim 2 dependent thereon lacks novelty.

Dependent claim 5 further defines claim 1. Fig.19 and page 19, lines 2-11 of the description of D1 discloses that a limiting portion 77a (equivalent to the locking pawl) limiting rotation is provided adjacent to the pivoting member 79 (equivalent to the pawl trigger arm) of the bracket 7B of the analysis sensing unit, that is to say, d1 discloses the additional technical features of claim 5. Accordingly, when claim 1 is not novel, claim 5 dependent thereon lacks novelty.

Dependent claim 10 further defines claim 1. Page 11, line 24-page 12, line 18 of the description of D1 discloses that the trigger mechanism is disposed to immobilize right after the set pressure is reached and initiate the lancing device, that is to say, d1 discloses the additional technical features of claim 10. Accordingly, when claim 1 is not novel, claim 10 dependent thereon lacks novelty.

4. Claims 3-4, 6-9 lack an inventive step under Article 22.3 of the Chinese Patent Law.

Dependent claims 3-4 are dependent claims of claim 2, and their additional technical features are: "the bias spring is configured to apply a pre-load force in the range of 3N to 13 N against the pressure tip" and "the bias spring is configured to apply a pre-load force in the range of 9N to 10 N against the pressure tip". However, D2 (see column 7, lines 58-65; column 8, lines 26-30 of the description) discloses the piercing device provides a pressure of 10-15N by using a spring to optimally control and operate the piercing device. Furthermore, these features play the same roles in D2 as in the present invention: to provide a pre-load force against the pressure tip. As taught by D2, a person skilled in the art can think of applying a pre-load force in the range of 3N to 13 N or 9N to 10 N against the pressure tip. Therefore, use of the

above additional technical means is obvious for a person skilled in the art. Accordingly, when claim 2 is not novel, claims 3-4 dependent thereon lack an inventive step.

Dependent claim 6 is a dependent claim of claim 5, and its additional technical features are: "the locking pawl includes pawl ratchet teeth and wherein the pressure tip includes pressure tip ratchet teeth". However, use of ratchet teeth in a locking pawl is technical means often used by a person skilled in the art. Accordingly, when claim 5 is not novel, claim 6 dependent thereon lacks an inventive step.

Dependent claim 7 is a dependent claim of claim 1, and its additional technical features are: "the trigger mechanism includes a frictional clutch for immobilizing the pressure tip". However, use of a frictional clutch in a brake structure is technical means often used by a person skilled in the art. Accordingly, when claim 1 is not novel, claim 7 dependent thereon lacks an inventive step.

Dependent claims 8-9 are dependent claims of claim 1, and their additional technical features are: "the trigger mechanism includes an optical relay switch, an electrical relay switch". However, use of a relay switch in a trigger structure is technical means often used by a person skilled in the art. Accordingly, when claim 1 is not novel, claims 8-9 dependent thereon lack an inventive step.

The applicant should make a response to all the problems specified in the Office Action herein within the prescribed time limit for response, and amend the application documents if necessary, otherwise, the present application is unlikely to be approved. Any amendments to the application documents should comply with Article 33 of the Chinese Patent Law and may not go beyond the scope of disclosure contained in the original description and claims.

Examiner: Lu Kai

Code number: 96D2